

Message

From: Martha M. Rumore [mrumore@frierlevitt.com]
Sent: 8/21/2020 4:18:49 PM
To: Charles Boyd [CharlesB@Safechain.com]; John E. Morrone [JMorrone@FrierLevitt.com]
CC: Donna Halpin [DHalpin@frierlevitt.com]
Subject: RE: Recall Memorandum Wholesaler 4821-9072-7880 v.1

Hi Charles:

Somewhere in this email, SafeChain should indicate that they assume Gilead has reported the incident to the FDA, is conducting an investigation, and SafeChain awaits further instructions from Gilead regarding this matter.

If you have any questions, do not hesitate to reach out to John to myself.

Best,

Martha

Martha M. Rumore, PharmD, JD
Senior Counsel

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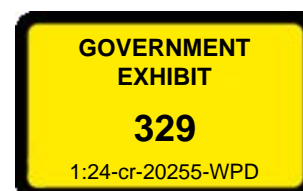
From: Charles Boyd <CharlesB@Safechain.com>
Sent: Friday, August 21, 2020 10:26 AM
To: John E. Morrone <JMorrone@FrierLevitt.com>
Cc: Martha M. Rumore <mrumore@frierlevitt.com>; Donna Halpin <DHalpin@frierlevitt.com>
Subject: RE: Recall Memorandum Wholesaler 4821-9072-7880 v.1

Hi John,

Below is the email I have drafted to send to Gileads QA team. Please let me know if you have any recommendations or changes. Thanks!

Hi Clifford,

We are still waiting on all of the details surrounding the complaint to better understand what happened. Here is what we know as of now.



GX 329.0001

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We received a complaint from our customer White Cross Pharmacy – Brawley, located in San Bernardino, CA regarding one sealed bottle of Biktarvy (NDC# 61958-2501-01). We are one of their 3 primary wholesalers who provides this product to them. We were notified by them on Monday that one bottle had supposedly been dispensed to a patient who discovered generic Excedrin in the bottle not Biktarvy. White Cross is still researching on their end and which wholesaler that product came from. The PIC at White Cross has filed a complaint with Gilead and shipped the product back to you. This is a different Lot# than what we asked you to verify and a picture of the bottle is provided below. After doing some additional due diligence on our end we discovered that we have distributed 44 bottles of this same Lot# to roughly 20 other customers, none of which had that same issue.

Safe Chain only receives and ships finished products as we are only licensed as a wholesale distributor not repacker. I am not certain how something like this could happen but am 100% certain it wasn't caused by any Safe Chain policies or procedures. We are more than happy to provide any additional information you may need. Please let us know how we can help or if you would like to setup a time to discuss further. Thanks and have a great day!

Best regards,
Charlie



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From: John E. Morrone <JMorrone@FrierLevitt.com>
Sent: Thursday, August 20, 2020 3:13 PM
To: Charles Boyd <CharlesB@Safechain.com>
Cc: Martha M. Rumore <mrumore@frierlevitt.com>; Donna Halpin <DHalpin@frierlevitt.com>
Subject: Recall Memorandum Wholesaler 4821-9072-7880 v.1

Charlie,

Here is the memo regarding the recall.

Very truly yours,

John E. Morrone, Esq.
Partner

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GX 329.0002

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GX 329.0003